| Notice of Allowability | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/519,035 | DE MEYER ET AL. | |
| | Examiner | Art Unit | |
| | Louise Humphrey, Ph.D. | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--*

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *6/19/06*.

2. ☒ The allowed claim(s) is/are *3,4,9 and 10*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   **Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

JEFFREY S. PARKIN, PH.D.
PRIMARY EXAMINER

## EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Laura Donnelly on 29 August 2006, followed by email confirmation on 30 August 2006.

Please cancel claims 1, 2, 5-8, and 11-20.

The application has been amended as follows:

3. A method for evaluating the effectiveness of a protease inhibitor as an antiviral therapy for a patient infected with at least one mutant HIV strain comprising:

(i) collecting a sample from an HIV-infected patient;

(ii) extracting the nucleic acid from said patient sample;

(iii) determining the amino acid sequence encoded by said nucleic acid'

(iv) determining whether said amino acid sequence comprises at least one mutation selected from R41S, R41T, R41I, R41G and K70E in the protease region;

(v) measuring the effectiveness of said protease inhibitor against said mutant HIV strain;

(vi) correlating the presence of said at least one mutation of step (iv) to a change in the effectiveness of said protease inhibitor against said mutant HIV strain relative to the

effectiveness of said protease inhibitor against a wild type HIV strain (HIV IIIB/LAI reference sequence).

4. A method for evaluating the effectiveness of a protease inhibitor as an antiviral therapy for a patient infected with at least one mutant HIV strain comprising:

(i) collecting a sample from an HIV-infected patient;

(ii) extracting the nucleic acid from said patient sample;

(iii) determining the amino acid sequence encoded by said nucleic acid;

(iv) determining whether said amino acid sequence comprises at least one mutation selected from R41T, R41I, R41G and K70E in the protease region;

(v) measuring the effectiveness of said protease inhibitor against said mutant HIV strain;

(vi) correlating the presence of said at least one mutation of step (iv) to a change in the effectiveness of said protease inhibitor for said patient relative to the effectiveness of said protease inhibitor for a patient infected with a wild type HIV strain (HIV IIIB/LAI reference sequence).

9. A method for evaluating a change in the susceptibility of a HIV strain to a protease inhibitor comprising the steps of:

(i) collecting a sample from an HIV-infected patient;

(ii) extracting the nucleic acid from said patient sample;

(iii) determining the amino acid sequence encoded by said nucleic acid;

(iv) determining whether said amino acid sequence comprises at least one mutation selected from R41S, R41T, R41G and K70E in the protease region;

(v) measuring the susceptibility of said HIV strain from said patient to said protease inhibitor;

(vi) correlating the presence of said at least one mutation of step (iv) to a change in susceptibility of the patient HIV strain to said protease inhibitor relative to the susceptibility of a wild type HIV strain (HIV IIIB/LAI reference sequence) to said protease inhibitor.

10. A method for evaluating a change in the susceptibility of a HIV strain to a protease inhibitor comprising the steps of:

(i) collecting a sample from an HIV-infected patient;

(ii) extracting the nucleic acid from said patient sample;

(iii) determining the amino acid sequence encoded by said nucleic acid;

(iv) determining whether said amino acid sequence comprises at least one mutation selected from R41T, R41G and K70E in the protease region;

(v) measuring the susceptibility of said HIV strain from said patient to said protease inhibitor;

(vi) correlating the presence of said at least one mutation of step (iv) to a change in susceptibility of the patient HIV strain to said protease inhibitor relative to the susceptibility of a wild type HIV strain (HIV IIIB/LAI reference sequence) to said protease inhibitor.

The following is an examiner's statement of reasons for allowance:

The objection to the specification **is withdrawn** in view of the Applicant's amendment.

The rejection of claims 3, 4, 9, and 10 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification commensurate in scope **is withdrawn** in view of the amendment.

The rejection of claims 3, 4, 9, and 10 under 35 U.S.C. §102(b) as being anticipated by Craig et al. (1998) **is withdrawn** in view of the amendment deleting the "41K" mutation.

Claims 3, 4, 9, and 10 are apparently free of prior art of the record. The closest prior art, Craig et al. (1998), does not teach or fairly suggest any of the mutations – R41T, R41S, R41I, R41G, and K70E – in HIV protease region.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jeffrey Parkin, Ph.D.
Primary Examiner
31 August 2006

8/31/2006